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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,393	04/27/2006	Marcos Isamat Riviere	6647/012	1396
22440	7590	05/30/2008	EXAMINER	
GOTTLIEB RACKMAN & REISMAN PC			KOSSON, ROSANNE	
270 MADISON AVENUE				
8TH FLOOR			ART UNIT	PAPER NUMBER
NEW YORK, NY 10016-0601			1652	
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			05/30/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/577,393	ISAMAT RIVIERE, MARCOS	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 August 2006.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-15 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-7 and 11-15, drawn to a method of identifying biological species or subspecies in a biological sample by performing PCR with primers that hybridize to regions 1130-1191 and 1453-1473 of the human beta-actin gene.

Group 2, claim(s) 1-6, 8 and 11-15, drawn to a method of identifying biological species or subspecies in a biological sample by performing PCR with primers that hybridize to regions 1453-1473 and 2041-2065 of the human beta-actin gene.

Group 3, claim(s) 1-6, 9 and 11-15, drawn to a method of identifying biological species or subspecies in a biological sample by performing PCR with primers that hybridize to regions 2433-2459 and 2643-2680 of the human beta-actin gene.

Group 4, claim(s) 1-6 and 10-15, drawn to a method of identifying biological species or subspecies in a biological sample by performing PCR with primers that hybridize to regions 2643-2680 and 2940-2960 of the human beta-actin gene.

The inventions listed as Groups 1-4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The requirement of unity of invention is not fulfilled because there is no technical relationship among these inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features. The technical feature that links the 4 groups of inventions is a method of identifying the animal species of the source of a piece of DNA in a biological sample by amplifying a region of the human beta-actin gene.

The inventions of Groups 1-4 do not share the common special technical feature of a method of identifying the animal species of the source of a piece of DNA in a biological sample by amplifying a region of the human beta-actin gene, because Lockley et al. ("Intron variability in

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an actin gene can be used to discriminate between chicken and turkey DNA," Meat Sci 61:163-168, 2002) disclose a PCR method for identifying the animal species that is a source of the DNA found in a biological sample by amplifying the  $\alpha$ -actin genes in the sample (see p. 163, right col., and p. 164, left col.). Lockley et al. improved on their prior art by developing a PCR method that distinguishes between chicken and turkey  $\alpha$ -actin genes (see p. 164, right col., and p. 165). Nakajima-Iijima et al. ("Molecular structure of the human cytoplasmic  $\beta$ -actin gene: interspecies homology of sequences in the introns," PNAS 82:6133-6137, 1985) disclose that the actins are the most abundant proteins in eukaryotic cells and that the amino acid sequences are highly conserved among different species of animals.  $\beta$ -actins have the advantage that they are non-muscle proteins and are present in all types of tissues, whereas other actins such as  $\alpha$ -actins are muscle proteins (see p. 6133, left col., and p. 6135). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the  $\beta$ -actin gene for the  $\alpha$ -actin gene in the method of Lockley et al. (amplify and screen for  $\beta$ -actin genes in a biological sample of unknown or suspect composition), because Nakajima-Iijima et al. disclose that the  $\beta$ -actin gene is present in all types of tissue. Thus, one of ordinary skill in the art would have known that if a biological sample contained DNA from one or more animals that was not of muscle tissue origin,  $\beta$ -actin DNA would have been detectable to indicate the source of the DNA, but not  $\alpha$ -actin DNA.

Thus, the technical feature of a method of identifying the animal species of the source of a piece of DNA in a biological sample by amplifying a region of the human beta-actin gene does not define the invention over the prior art. Because the common technical feature is not inventive (special) with respect to the cited references, it is clear that the claims of Groups 1-4 lack a single common technical feature that defines them over the prior art.

If Group 1 is elected, claim 11 will be examined to the extent that it reads on a method of using primers P1 and P2. If Group 2 is elected, claim 11 will be examined to the extent that it reads on a method of using primers P3 and P4. If Group 3 is elected, claim 11 will be examined to the extent that it reads on a method of using primers P5 and P6. If Group 4 is elected, claim 11 will be examined to the extent that it reads on a method of using primers P7 and P8. This arrangement matches the different claimed polynucleotides with their respective inventions.

Applicants must choose **ONE** pair of polynucleotides from among those claimed as indicated in the different groups above. Each sequence is a distinct invention requiring separate searches. THESE ARE NOT SPECIES. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, each of the polynucleotides is patentably distinct. Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation, obviousness and double patenting. Hence, the search for even two different polypeptides or polynucleotides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

**Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be**

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**traversed (37 CFR 1.143).**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson  
Examiner, Art Unit 1652

rk/2008-05-20

/JON P WEBER/  
Supervisory Patent Examiner, Art Unit 1657